

REMARKS

Applicant has considered the non-final office action mailed July 11, 2011 in connection with the Application. Applicant thanks the Examiner for withdrawing various rejections of record in light of Applicant's December 22, 2010 response.

Reference herein to pages and line numbers of the specification of the Application are with respect to the specification of international application no. PCT/GB04/05030, of which the Application is the U.S. national phase.

Amendments to the Claims

Claims 1 – 29 are pending in the Application prior to entry of the Amendments herein.

In the instant section, it is to be assumed that reference herein to a single portion of the specification in support of a particular amendment or new claim, is not to preclude the existence of additional support for that amendment or claim, but located elsewhere in the specification and drawings, and not specifically referenced herein.

Claims 7 – 14, 18, and 21 – 29 are cancelled herein without prejudice to Applicant's rights to pursue the subject matter of the claims in one or more continuing applications that benefit of the right of priority of the Application.

Claims 3 and 5 are amended to exclude various substituents and to delete exemplary limitations, as well as to recite a di-substitution requirement for R¹. Support for such amendments can be found in Applicant's specification at, for example, page 10, lines 20 – 23, as well as in original claims 10 and 11 in the preceding PCT application, when read in conjunction with Formula (I) itself.

Claims 15 – 17 are amended to attend to matters of antecedent basis necessitated by the amendments to claims 3 and 5.

An Applicant may decline to claim any material disclosed in his specification. MPEP 2173.05(i); *In re Johnson*, 558 F.2d 1008, 1019, 194 USPQ 187,196 (CCPA 1977) (alternative elements positively recited in the specification may be explicitly excluded in the claims).

Claim 20 is amended to delete a parenthetical limitation.

New claims 30 – 33 recite the subject matter of exemplary features deleted from claims 3 and 5.

New claim 34 recites a limitation deleted from claim 20.

Accordingly, no new matter is introduced by way of the claim amendments and new claims herein, and entry thereof is respectfully requested.

REJECTIONS OF THE CLAIMS

Rejections under 35 U.S.C. § 112 (¶ 2)

The Examiner has rejected claims 3, 20, 27, and 29 under 35 U.S.C. § 112 (second paragraph) for “contain[ing] parenthetical information which renders the claims vague and indefinite”.

The amendments herein to claims 3, and 20 (as well as to claim 5), which remove the exemplary limitations, and the cancellation herein of claims 27 and 29, effectively moots the rejection.

Rejections under 35 U.S.C. § 112 (¶ 1)

New matter

The Examiner has rejected claim 5 under 35 U.S.C. § 112 (first paragraph) as allegedly “containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s) ... had possession of the claimed invention”. Specifically, the Examiner objected to the limitation that excluded “*ter*-butyloxy” from the substituent list.

Applicant has deleted herein the offending limitation and, therefore, respectfully traverses the rejection.

Scope of Enablement

The Examiner has rejected claims 3, 4, and 7 – 26 under 35 U.S.C. § 112 (first paragraph) as allegedly being based on a disclosure that is not enabled commensurate in scope with the claims. Applicant respectfully traverses the rejection.

It is unclear to Applicant, from a reading of the Examiner’s rejection, whether the Examiners’ underlying contention is that the specification does not enable the full genus of compounds, or whether the specification does not enable treatment of the full list of disease states.

Applicant notes that claims 3 – 6 and 15 – 17 do not recite specific disease states. Such claims are enabled even if only a single disease state is enabled.

Applicant notes further that those claims are also amended herein to recite a smaller genus of compounds than those previously contemplated.

Nevertheless, Applicant respectfully submits that the compounds of the claimed invention would be understood by the skilled person based on the specification of the Application to be clearly disclosed as anti-inflammatory agents. In particular, these compounds have been newly

found by the Applicant to be useful in the treatment of “temporally or spatially inappropriate inflammatory responses [which] play a part in a wide range of diseases” (see page 1, lines 5-6 of the Application specification). The surprising and useful properties of the anti-inflammatory agents which are compounds of general formula (I) include the following:

“They are stable in human serum and consequently have excellent pharmacokinetic properties; they are orally bioavailable; they are highly potent broad-spectrum chemokine inhibitors in vitro with excellent selectivity over non-chemokine chemoattractants; they are highly potent and effective anti-inflammatory agents in vivo in rodent models of inflammation ***. Taken together, these properties suggest that amide derivatives of 3-aminocaprolactam represent, anti-inflammatory medications with advantages over previously described compounds”
(specification of the Application, at page 10, lines 5 – 15).

Additionally, the compounds “are relatively inexpensive to synthesise, using facile synthesis routes provided herein” and “their administration is not associated with any significant acute toxicity at the doses necessary to achieve a maximal therapeutic effect” (Specification of the Application, at page 10, lines 5-15).

Furthermore, the range of diseases specified, for example, in claim 19 all have in common that they have an inflammatory component which can be treated by compounds of the present invention. Whether these diseases have different underlying causes is not relevant here, as it is the inflammatory component of the disease which can be successfully treated by the claimed compounds and compositions regardless of the mechanism of the underlying disease. Indeed, the method of claim 20 (on which claim 19 depends) is explicitly directed to treatment or amelioration of the *symptoms* of an inflammatory disease.

Accordingly, and noting that claims 7 – 14, 18, and 21 – 26 are cancelled herein, Applicant respectfully requests that the Examiner withdraws the rejection of claims 3 – 6, 15, 16, 17, 19 and 20 under 35 U.S.C. § 112 (first paragraph) as not enabled commensurate with their scope.

Rejections under 35 U.S.C. § 102

“A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). Applicant

respectfully points out that Seiffert neither discloses each and every element of Applicant's claims as amended herein, nor describes Applicant's invention in complete detail.

Rejection over Davidson

The Examiner has rejected claims 5, 6, and 27 – 29 under 35 U.S.C. § 102(b) as allegedly being anticipated by Davidson *et al.*, *Tetrahedron*, Vol. 49 (30), pp. 6569, (1993) ("Davidson", hereinafter). Applicant respectfully traverses the rejection.

First, claims 27 – 29 are cancelled herein.

Second, regarding claims 5 and 6, the Examiner identifies two compounds on p. 6569 of Davidson as allegedly anticipating Applicant's claims.

Claims 5 and 6 as amended herein recite a genus of compounds in which the group R¹, which occupies the same position as the group "R" in Davidson, has a di-substitution at the atom that bonds to the carbonyl group (X in Applicant's claimed formula).

Accordingly, Applicant respectfully submits that the disclosure of Davidson does not anticipate Applicant's claims 5 and 6, as amended herein, and respectfully requests that the rejection be withdrawn.

Rejection over JP 2003-145933

The Examiner has rejected claims 5, 6, and 27 – 29 under 35 U.S.C. § 102(a) as allegedly being anticipated by JP 2003-145933. Applicant respectfully traverses the rejection.

First, claims 27 – 29 are cancelled herein.

Second, regarding claims 5 and 6, the Examiner identifies a compounds on p. 6 of JP 2003-145933 as allegedly anticipating Applicant's claims.

Claims 5 and 6 as amended herein recite a genus of compounds in which the group R¹, has a di-substitution at the atom that bonds to the carbonyl group (X in Applicant's claimed formula). By contrast, the corresponding group in JP 2003-145933 is a straight chain alkyl group.

Accordingly, Applicant respectfully submits that the disclosure of Davidson does not anticipate Applicant's claims 5 and 6, as amended herein, and respectfully requests that the rejection be withdrawn.

By responding in the foregoing remarks only to particular positions taken by the examiner, Applicant does not acquiesce with other positions that have not been explicitly addressed. In addition, Applicant's selecting particular arguments for the patentability of a claim should not be

understood as implying that no other reasons for the patentability of that claim exist. Finally, the Applicant's decision to amend or cancel any claim should not be understood as implying that the applicant agrees with any positions taken by the examiner with respect to that claim or other claims affected by such amendments.

CONCLUSION

In view of the above remarks, Applicant respectfully submits that the Application is in good and proper order for allowance. Withdrawal of the Examiner's rejections and early notification to this effect are earnestly solicited. If, in the opinion of the Examiner, a telephone conference would expedite the prosecution of the Application, the Examiner is encouraged to call the undersigned at (650) 419-2010.

No fee is believed owed in connection with filing of this amendment and reply, other than the extension of time fees, separately authorized herewith.

Respectfully submitted,

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